Exhibit K

Comparison of Forced Air and Conductive Heating Systems during Out-Patient Orthopaedic Surgeries

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Background: It is critical to maintain a normal or near-normal body temperature during and after surgery. Traditionally this has been done using a forced air device. One of the main concerns with forced air devices is that they may increase bacterial contamination in the surgical field before and during surgery. Recently, conductive heating systems have been developed and used to address these concerns. While these devices do not disrupt airflow at the surgical site, their efficacy versus forced air devices has not been extensively studied.

Purpose: The purpose of this study is to compare the efficacy of a forced air device to a conductive heating device in their ability to maintain perioperative patient normothermia.

Methods: 50 patients undergoing outpatient orthopaedic procedures were randomized into either the Forced Air group (FA) or Conductive Heat group (CH). In the patients randomized to the FA group, a Bair Hugger™ (Arizant Medical, Inc., Eden Prairie, Minnesota) forced-air cover was positioned over the upper body (if lower extremity surgery) or lower body (if upper extremity surgery). In patients assigned to the CH group, a VitaHEAT Medical ®(VitaHEAT Medical, LLC , Rolling Meadows, IL) conductive heating device was placed under the torso of the patient. Patients in both groups were otherwise draped per surgical routine. Ambient temperature was maintained near 20°C. Demographic and morphometric characteristics were recorded. Patient temperature was recorded at 15 minute intervals throughout the surgery and throughout the recovery room stay. Intraoperative and recovery room temperatures between the two groups were compared using a student's T-test.

Results: No statistically significant difference in mean intra-operative temperatures was found between the two groups (FA 97.95 and CH 97.64, p=.063). No statistically significant difference in mean recovery room temperatures was found between the two groups (FA 97.68 and CH 97.53, p=.39).

Conclusion: There was no difference between intra-operative and recovery room temperatures between patients using either a forced air device or a conductive heating device. Those involved in perioperative care should be familiar with conductive heating devices as an alternative to traditional forced air devices.

It is critically important to maintain a normal or near-normal body temperature during and after surgery. During surgical procedures, patients' core body temperatures decrease which can lead to perioperative hypothermia (perioperative core temperature <36.0° C).[1] The cause of the decrease in body temperature is multi-factorial with one of the main reasons being thermal redistribution. Thermal redistribution occurs after the induction of anesthesia and can account for up to 1.6° C decrease in the core body temperature.[1, 21] This decrease in core body temperature can then lead to significant complications. Reported complications of hypothermia include impaired wound healing, prolonged drug action, negative postoperative nitrogen balance, coagulopathies, cardiac events and increased duration of hospital stay.[9, 11, 14-16, 23, 24] In fact, a 1.9° C core hypothermia was found to triple the incidence of surgical wound infection after colon resection and increase the hospital stay by 20%.[15, 19] For these reasons, the maintenance of perioperative normothermia has rightfully become a priority of anesthesiologists, surgeons and the entire surgical team.

Many strategies have been employed to maintain a normal body temperature during the surgical period. These include: pre-warming, fluid warming, forced-air devices, conductive heating devices, increasing the ambient temperature, covering the body as much as possible and others.[10, 13, 24]

Forced air devices have been studied and demonstrated to help decrease postoperative hypothermia.[3, 22] Conductive heating devices have also been studied with demonstrated efficacy.[6, 17] There is concern that conductive warming devices may be less effective as they

primarily function by warming the back and torso which may be a less efficient method of heat exchange than warming the extremities.[7, 8, 18] While this concern has been raised, it has not been extensively studied or proven in a clinical setting.

Recently, it has been demonstrated that forced air devices may interfere with laminar flow conditions in orthopaedic operating rooms potentially introducing contaminants around the surgical site and increasing infection rates.[2, 12]

The purpose of this study is to compare the efficacy of a forced air device to a conductive heating device in their ability to maintain perioperative patient normothermia during outpatient orthopaedic surgeries.

Methods

Fifty patients undergoing outpatient orthopaedic surgeries were randomized into either the Forced Air group (FA) or Conductive Heat group (CH). Randomization was performed using a random number generator. All necessary approvals were obtained from the local Institutional Review Board.

In the patients randomized to the FA group, a Bair Hugger™ (Arizant Medical, Inc., Eden Prairie, Minnesota) forced-air cover was positioned over the upper body (if lower extremity surgery) or lower body (if upper extremity surgery). In patients assigned to the CH group, a VitaHEAT

Medical ® (VitaHEAT Medical, LLC, Rolling Meadows, IL) conductive heating device was placed under the torso of the patient.

Patients in both groups were otherwise draped per surgical routine. Ambient temperature was maintained near 20°C. Demographic and morphometric characteristics were recorded. Patient temperature was recorded at 15 minute intervals throughout the surgery and throughout the recovery room stay.

Intraoperative and recovery room temperatures between the two groups were compared using a student's T-test.

Results

There were no differences noted in demographics between the two groups (Table 1).

No statistically significant difference in mean intra-operative temperatures was found between the two groups (FA 97.95 and CH 97.64, p=.063). No statistically significant difference in mean recovery room temperatures was found between the two groups (FA 97.68 and CH 97.53, p=.39) (Figure 1).

Discussion

It is widely agreed upon that maintaining a normal perioperative temperature is beneficial to the patient for many different reasons. Nevertheless, discussion continues about the optimal way to perform patient warming. In this study, two methods of patient warming are compared: forced air and conductive heat. We found no statistically significant difference between the two methods in this patient population.

Others have studied the effects of these two heating methods in both laboratory and clinical settings.[3-6, 20] In a study using healthy volunteers, Brauer et al concluded that "...a gel-coated circulating water mattress placed only on the back cannot replace a forced-air warming system."[5] Buisson et al studied the warming potential of both a forced air device and a conductive warming devices during abdominal surgeries in neonates and found forced air warming to me more effective.[8] Several studies have looked at conductive warming devices and found them to be effective as well.[6, 17, 18] Ruetzler et al compared a conductive warming device to a forced air device in a randomized trial of patients undergoing abdominal surgery.[20] They found that the two systems transferred comparable amounts of heat and both were suitable for maintaining normothermia even during long operations.

There are certainly pros and cons to both forced air and conductive warming devices. Most conductive warming devices are placed on the torso of the patient and therefore may be inherently less effective as vasodilation occurs after the induction of anesthesia making

peripheral warming potentially superior. Forced air devices have the potential for increasing contaminants at the surgical site. Forced air devices have been shown to generate convection current in the vicinity of the surgical site which could disrupt ventilation systems designed to prevent infection.[12] In another study, forced air devices were demonstrated to disrupt ventilation airflows over the surgical site while conductive warming devices had no demonstrable effect.[2]

In this study we sought to compare the efficacy of a conductive heating device and a forced air device in maintaining perioperative normothermia during outpatient orthopaedic surgery. Our study reveals equivalent abilities of these two modalities in maintaining perioperative normothermia with no statistically significant differences between the two groups.

This study has several limitations. Firstly, temporal temperatures were used. This is not an accurate measure of core body temperature but we believe that by using a consistent method of temperature measurement between the two groups we are able to compare the efficacy of the two even though we are measuring a proxy of core body temperature. In addition, this is the temperature that is typically monitored by anesthesiologists and the perioperative team in this setting and thus represents a clinically relevant measure. Secondly, the sample size of this study is limited and it is possible that a larger study may reveal additional information or potentially differences between the groups. Thirdly, it is important to note that there is likely not a single best solution to the perioperative warming issue. Every surgery is different and warming ability depends upon the procedure and setting. For example, an orthopaedic

surgeon performing joint replacements may be particularly concerned about disruption to laminar flow and potential for increased infection. Conversely, during surgeries that involve prepping and draping of the torso, forced air devices that cover the extremities may be more desirable.

In summary, we have demonstrated equivalent efficacy of forced air and conductive warming devices in maintaining intra-operative and post-operative normothermia in an outpatient orthopaedic surgery center.

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Table 1: Patient Demographics

	Bair Hugger	VitaHeat	p value
Males	65%	59%	
Females	35%	41%	
Age (years)	53.00	50.46	0.53
BMI	29.84	28.87	0.98

Figure 1: Comparison of Mean Intra-Operative and Recovery Room Temperatures between the Groups